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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,735

06/14/2006

Christian Hummel

50151

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1609

7590

12/15/2008

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WASHINGTON,, DC 20036

EXAMINER

OU, JING RUI

ART UNIT

PAPER NUMBER

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MAIL DATE

DELIVERY MODE

12/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,735	Applicant(s) HUMMEL ET AL.	
	Examiner JING OU	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/22/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is responsive to the amendment file September 22, 2008. Claims 11-28 are pending. Claims 1-10 are cancelled. Claims 11, 14, and 23 are independent.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

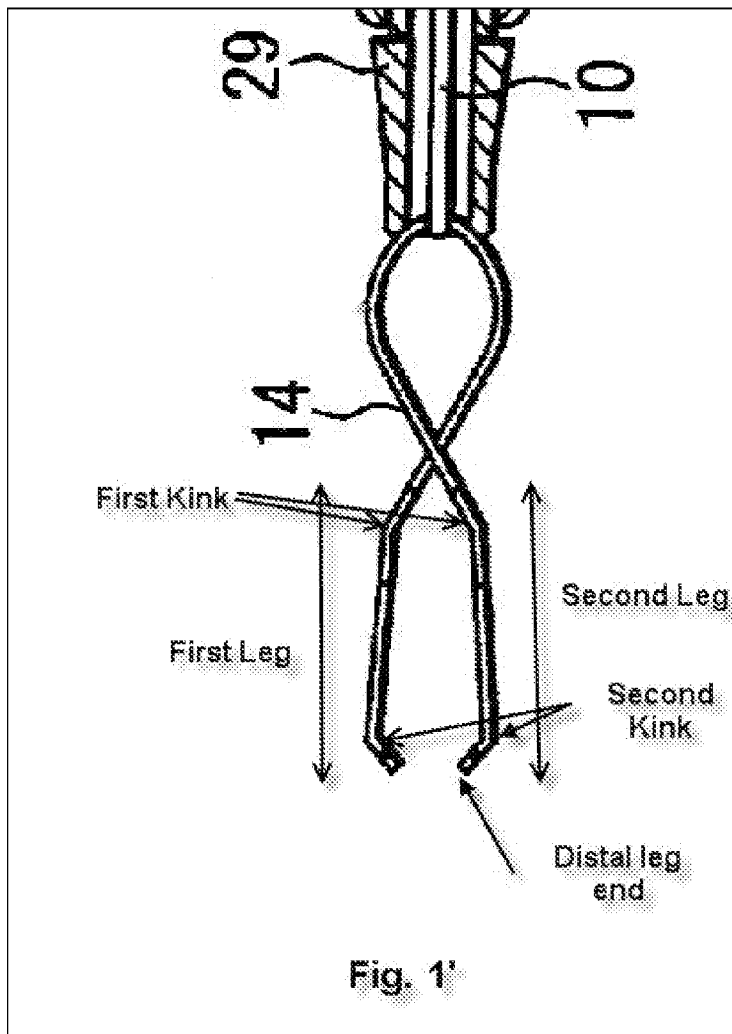
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 11-18, 20, 21, and 23-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Kobayashi et al (US Pub. No.: 2002/0128667).

In regard to Claims 11-13, Kobayashi et al discloses a method a method for self-closing medical clips, comprising the steps of: placing a distal end of a catheter tube (1, Figs. 21A-21D) in a body of a living being to be treated (Para.[0163]); arranging at least one self-closing medical clip (14) with relatively movable legs (see Figure 1' below) in the catheter tube adjacent the distal end by an operator located on a proximal end of the catheter tube (Para.[0163], there must be a operator located on the proximal end of the catheter tube for extruding the compression member 11 in the distal end direction.), the clip having a first kink in a first area of each leg extending outwardly and increasing a distance between the legs and a second kink in a second area nearer a distal leg end of the clip than the first area but spaced from the distal leg end extending inwardly and forming a point of mutual support for the legs (see Figure 1' below, the second kink extends inwardly to form a point of mutual support for the legs to grip onto the tissue as

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shown in Fig. 21D); pushing the clip out of the distal end (Figs. 21A-21B); opening the clip by an actuator (combination of manipulating wire 9, clip tightening ring 29, and 11 Figs. 21A-21D) having an actuating element (manipulating wire 9) acting on the clip, being movable longitudinally in the catheter tube, being actuated by the operator (Paras. [0092], [0096], and [0163]-[0166], as the compression member moves, the manipulating wire would be moved and actuated) and having a control part (beveled distal end of 29 acts as a control part, Fig. 19) converting an actuating force of the actuating element into a motion opening the legs of the clip (Paras.[0165]-[0166] and Figs. 21A-21D); and detaching the actuating element from the clip after opening of the clip to release and close the legs of the clip to apply the clip (Paras.[0165]-[0167] and Figs. 21A-21D); wherein the legs of the clip are symmetrical, are mirror images of one another and do not cross one another (Figs. 21A-21D); and wherein a plurality of other clips, similar to the one clip, are arranged in succession in the catheter tube (Figs. 21A-21D); and after application of the clip at the distal end of the catheter tube, the actuating device is functionally linked to the clip next following in the catheter tube (Paras.[0165]-[0167] and Figs. 21A-21D).



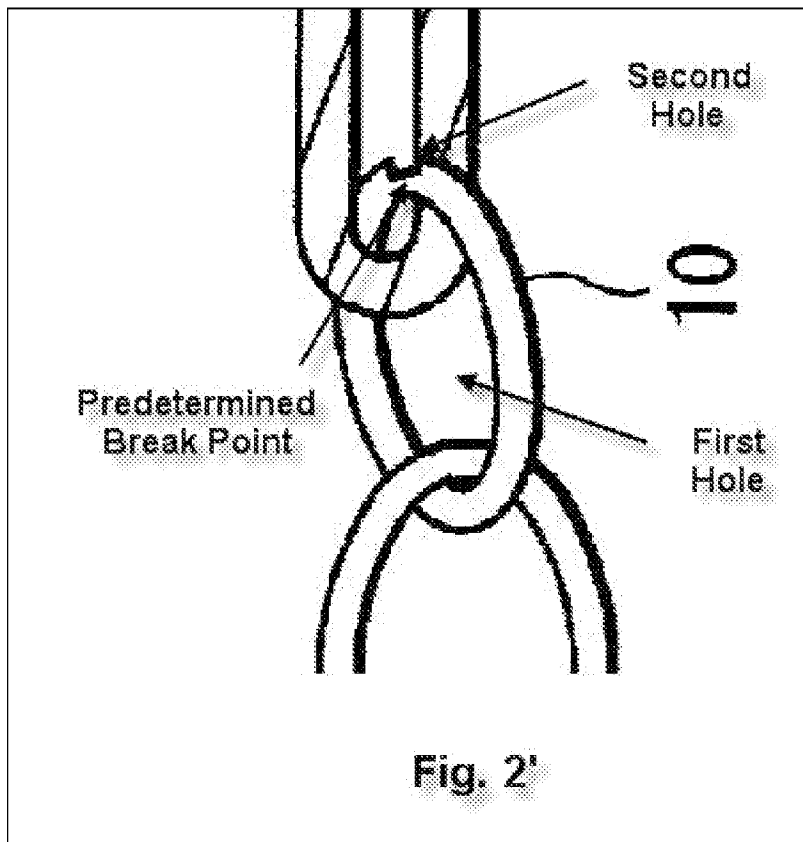
In regard to Claims 14-18, 20, 21, and 23-28, Kobayashi et al discloses a device comprising: a catheter tube (1, Figs. 21A-21D) having a distal end placeable in the body and a proximal end placeable outside the body; an operator at said proximal end (Para.[0163], there must be a operator located on the proximal end of the catheter tube for extruding the compression member 11 in the distal end direction.); an actuator extending in said catheter tube from said operator in an area adjacent said distal end (combination of manipulating wire 9, clip tightening ring 29, and 11, Figs. 21A-21D), having an actuating element movable longitudinally in said catheter tube and controlled

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by said operator, and having at least one control part with a distal end edge on a sleeve-shaped receiving part (clip tightening ring, 29, Fig. 21A); and at least one clip (14, Fig. 21A) adjacent to and directly engaging said distal end edge and having a part received in said actuating element and two adjacent legs (Fig. 21A and Figure 1' above), said legs having first kinks extending outwardly and increasing a distance between said legs in first areas of said legs and second kinks extending inwardly and forming a mutual support for said legs in second areas of said legs nearer to a distal leg end of said clip than said first area, but spaced from said distal leg end without said legs crossing one another (see Figure 1' below, the second kink extends inwardly to form a point of mutual support for the legs to grip onto the tissue as shown in Fig. 21D. The legs do not cross one another because as shown in Figure 1' above); whereby said legs are opened by said first kinks engaging said control part when said clip is inserted into said sleeve-shaped receiving part which converts an actuating force of said actuating element into an opening motion of said legs with said second areas engaging one another (Figs 21A-21D); wherein said actuating element comprises a pulling element (manipulating wire, 9, Fig. 21A); and said distal end edge comprises a beveled control surface; wherein said pulling element comprises a pull cable; and said clip is connected to said pull cable by a rear end crosspiece (ligating wire, 10, Fig. 21A) connecting said legs of said clip, said rear end crosspiece having two adjacent through holes (see Fig. 2' below) through which said pull cable extends in a loop connecting an advancing strand (either strand of the manipulating wire 9, Fig. 21A) extending from said operator to said rear end crosspiece to a retreating strand (the other strand of the manipulating wire 9,

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Fig. 21A) extending to said operator from said rear end crosspiece; wherein said rear end crosspiece comprises a section between said through holes forming a predetermined breaking point (see Fig. 7C and Fig. 2' below, the predetermined breaking point is located between the through holes.) fracturable by a pulling force of said pull cable via said loop thereof to detach said pull cable from said clip; wherein a blocking element (the tapered distal end tip 2 on the distal end of the catheter tube 1 is capable of permitting passage of the 29 with the respective clip only in the exit direction forward but against the motion affected by the pulling force of the manipulating wire 9) is located on said distal end of said catheter tube, said blocking element permitting passage of said sleeve-shaped receiving part only in an exit direction forward from said catheter tube and supporting said sleeve-shaped receiving part against motion rearwardly into said catheter tube effected by the pulling force of said pull cable; wherein at least one other clip and at least one other control part (Fig. 21A), similar to said one clip and said one control part, respectively, are mounted in succession with said one clip and said one control part in said catheter tube (Fig. 21A); and said advancing strand and said retreating strand extend through respective through holes in a rear end crosspiece joining legs of said other clip; and wherein said actuator comprises a tube (compression member, 11, Fig. 21A) movable in said actuator tube and having an end edge forming a plunger contacting a facing back end of said sleeve-shaped receiving part.



Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
7. Claims 19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al (US Pub. No.: 2002/0128667) as applied to claim 6 above, and further in view of Kimura et al (US Pub. No.: 2002/0045909).

In regard to Claims 19 and 22, Kobayashi et al discloses all the limitations as taught in Claim 6 and further discloses a collet (distal end tip, 2, Fig. 21A) and an axially projecting shoulder (expansion pieces, 31b, Fig. 22D, the expansion pieces is capable of centering in the collet-like end part of distal tip end) located at the back end of the sleeve-like receiving part. However, Kobayashi et al does not appear to disclose that the collet has longitudinal jaws.

However, Kimura et al explicitly teaches a collet (coil pipe, 13, Fig. 7A) for attaching to the distal end of a catheter tube of a clip applier has longitudinal jaws (arm sections, 13d, Fig. 7A).

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Kobayashi et al and Kimura et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teaching of Kobayashi et al and Kimura et al before him or her, to modify the collet of Kobayashi et al to include the jaws as taught by Kimura et al.

The suggestion/motivation for doing would have been to allow the diameter of the smaller diameter section (Kimura et al, 13a, Fig. 7A) to be expanded and contracted (Kimura et al, Para.[0162]). It is also old and well known in the art that such jaws would provide a more flexibility to the collet having a solid ring.

Therefore, it would have been obvious to combine Kimura et al with Kobayashi et al to obtain the invention as specified in the instant claims.

Response to Arguments

8. Applicant's arguments with respect to claims 11-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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JO

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773